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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary

Application No.	Applicant(s)	
10/799,999	MILLER ET AL.	
Examiner	Art Unit	_
KENDRA D. CARTER	1617	

		KENDRA D. CARTER	1617	
Period fo	The MAILING DATE of this communication app	ears on the cover sheet with the o	correspondence ad	dress
A SH WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY HEVER IS LONGER, FROM THE MAILING DA sisons of time may be available under the provisions of 37 CFR 1.1 SN (6) MONTHS from the mailing date of this communication, period for reply is specified above, the maximum statutory period to reply with the set or extended period for reply will by statute, sply received by the Office later than three months after the mailing dq patient term adjustment. See 37 CFR 1.70(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tir- till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this c D (35 U.S.C. § 133).	
Status				
2a)⊠	Responsive to communication(s) filed on <u>15 Fe</u> This action is FINAL . 2b) This Since this application is in condition for allowan closed in accordance with the practice under E	action is non-final. ace except for formal matters, pro		e merits is
Dispositi	on of Claims			
5)□ 6)⊠ 7)□	Claim(s) 1-11 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) 1-11 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or			
Applicati	on Papers			
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a)_ acce Applicant may not request that any objection to the c Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Ex-	epted or b) objected to by the drawing(s) be held in abeyance. Se on is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 Cl	
Priority u	ınder 35 U.S.C. § 119			
a)[Acknowledgment is made of a claim for foreign All b) □ Some * o) □ None of: 1. □ Certified copies of the priority documents 2. □ Certified copies of the priority documents 3. □ Copies of the certified copies of the prior application from the International Bureau see the attached detailed Office action for a list of	s have been received. s have been received in Applicative documents have been received (PCT Rule 17.2(a)).	ion No ed in this National	Stage
Attachmen	t(s)			
1) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation-Disclosure-Statement(s) (PTO/SE/08)	4) Interview Summary Paper No(s)/Mail D Notice of Informal F	ate	

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

Paper No(s)/Mail Date _____.

6) Other: _____

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DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of February 15, 2008 made to the office action filed July 30, 2007. Claims 1-11 are pending. Claims 1, 7, 9, 10 and 11 are amended.

In light of the amendments, the following rejections are withdrawn: 1) the 35 USC 112, second paragraph rejection of claim 11; 2) the 35 USC 112, first paragraph rejection of claim 11; 3) the 35 USC 112, first paragraph rejection of claims 1, 4 and 5; and 4) the 35 USC 103(a) rejection of claims 1-7, 9 and 10 as being unpatentable over Maibach et al. in view of Raz et al..

For the reasons in the previous office action and below, the Applicant's arguments of the following rejections were found not persuasive, thus the rejections are upheld: 1) the 35 USC 112, first paragraph rejection of claims 2, 3 and 6-11; 2) the obvious double patenting rejections of claims 1-5 as being unpatentable over copending applications 11/091,037, 11/358,017 and 10/808,004; and 3) the 35 USC 103(a) rejection of claims 8 and 11 as being unpatentable over Yu et al. in view of Maibach et al.

Due to the amendment to the claims, the new and modified 35 USC 103(a), obvious double patenting and 35 USC 112, first paragraph rejections are made below.

The Applicant's arguments are addressed below.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application daim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 USPQ24 2010 (Fed. Cir. 1993); In re Goodman, 11 F.3d 1046, 29 USPQ24 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11-16 of copending Application No. 11/091037 ('037).

Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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The application '037 teaches a method of reducing, reversing or preventing scarring of a subject's skin resulting from a surgical wound, the method comprising topically applying to the scarred skin at the site of the surgical wound an IRM compound in an amount effective to improve the quality of the skin (see claims 1 and 11). The IRM compound is an agonist of at least one TLR, specifically TLR7, TLR8 or both TLR7 and TLR8 (see claims 2, 3, 12 and 13). The method is administered via a topical application vehicle comprising a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil (see claims 4, 5, 14 and 15). The IRM compound is an imidazoquinoline amine, a tetrahydroimidazooquinoline amine, an imidozopyridine amine, and others disclosed in claims 6 and 16).

The application '037 does not teach that the improvement to the quality of the skin is by reversing changes in the dermis selected from the group consisting of diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, or a combination thereof.

To one of ordinary skill in the art, it would be obvious that the quality of skin is by the several changes as listed above because these are all effects of improving the quality of the skin, which will obviously occur upon reducing, reversing or preventing scarring of a subject's skin resulting from a surgical wound (i.e. improving the quality of skin).

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(2) Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-7 of copending Application No. 11/358.017 ('017).

Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '017 teaches a method of restoring at least a portion of diminished contact hypersensitivity administering an immune response modifier compound selected from the group consisting of an imidozoquinoline amine and others disclosed in claims 1 and 5. The immune response modifier compound is an agonist of at least one TLR, specifically TLR7, TLR8 or TLR9 (see claims 3 and 4). The method is administered via a topical application vehicle comprising a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil (see claims 6 and 7).

The application '017 does not specifically teach a method of improving skin quality is by reversing changes in the dermis selected from the group consisting of diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy

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of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, or a combination thereof.

To one of ordinary skill in the art, it would be obvious to improve the quality of the skin because upon treating a skin disorder such as contact hypersensitivity, one would improve the skin quality. In regards to how the quality of skin is improved, as listed above, all of the improvements are effects of improving the quality of the skin, which will obviously occur upon treating a skin disorder such as contact hypersensitivity (i.e. improving the quality of skin).

(3) Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 10, 18, 19, 21, 25, and 27 of copending Application No. 10/808,004 ('004).

Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The application '004 teaches a method of treating superficial basal cell carcinoma in a subject comprising administering an effective amount of the IRM compound imiquimod topically on the lesions (see claim 27). In regards to the IRM compound being an agonist of TLR7, TLR8 or both, this limitation is taught because

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the applicant's elected compound, imiquimod, is disclosed in claim 27 and thus has the same properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

The application '004 does not specifically teach a method of improving skin quality, but upon treating the skin disorder superficial basal cell carcinoma, one would improve the skin quality. The application '004 also does not teach that the improvement to the quality of the skin is by reversing changes in the dermis selected from the group consisting of diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, or a combination thereof.

To one of ordinary skill in the art, it would be obvious that the quality of skin is by the several changes as listed above because these are all effects of improving the quality of the skin, which will obviously occur upon treating the skin disorder superficial basal cell carcinoma (i.e. improving the quality of skin).

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The application '004 also does not specifically teach that the application vehicle comprises a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil. To one of ordinary skill in the art would find it obvious to formulate the topical method of '004 to comprise a cream, foam, gel, spray, ointment, lotion, solution, suspension, dispersion, emulsion, microemulsion, past, powder, wipe or oil because these are forms of topical formulations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description on how to administer all of the different types of classes of IRM compounds (even those that are TLR7 agonist) other than imiguimod.

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For instance, the differences in structural features of the different classes of compounds disclosed in claims 6-11 will result in different reactivity, solubility, bioavailability, etc. Thus, by virtue of the different structures and reactivity of these compounds, the efficacy will inherently be different. One would need to perform further experimentation to acquire the effectiveness and the amounts of each IRM compound in prior art in order to practice the invention. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for yaque intimation of general ideas that may or may not be workable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.

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Resolving the level of ordinary skill in the pertinent art.

Considering objective evidence present in the application indicating

obviousness or nonobviousness.

(1) Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Maibach et al. (US 2003/0072724 A1) in view of Yu et al. (US

6,335,023 B1), in further view of Raz et al. (US 2004/0248837 A1).

Maibach et al. teaches a treatment of an individual predisposed to or afflicted

with skin hyperpigmentation, and comprises topically administering to the individual's

affected skin area a pharmaceutical formulation containing a therapeutically effective

amount of an agent active for treating skin hyperpigmentation (see page 4, paragraph

44, lines 1-7). A preferred embodiment is the treatment of age spots, which is age-

related and hence is common among the elderly (see page 5, paragraph 45, lines 5-8).

Active agents include any compound that effectively treats warts such as imiguimod

(see page 8, paragraph 92, lines 1-3 and 7; addresses claims 1, 6, 4, 7, 9 and 10).

Treatment is to improve or remediate damage, which is exemplified in examples 4 and 5

by the lightened skin regaining essentially normal skin color after eight weeks of

treatment (i.e. visibly reducing a skin change associated with aging and improving the

quality of the skin; addresses claims 1, 7, 9 and 10). The formulation may be in any

quality of the only addresses stating 1, 1, 5 and 10,1 the formalianer may be in any

form suitable for application to the body surface such as a cream, lotion, solution, gel,

ointment, paste, or the like (see page 9, paragraph 100, lines 1-4; addresses claim 5).

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Maibach et al. does not teach the IRM compound imiquimod is an agonist of at least one TLR, specifically TLR7, TLR8 or both. Maibach et al. also does not teach that the improvement to the quality of the skin is by reversing changes in the dermis selected from the group consisting of diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, or a combination thereof.

Yu et al. teaches a method of treating cosmetic conditions or dermatoligical disorders comprising topically applying a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42). Cosmetic conditions or dermatological disorders include changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40). Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42).

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Raz et al. teaches that a TLR agonist is any compound or substance that functions to activate a TLR, e.g. to induce a signaling event mediated by a TLR signal transduction pathway. An example of a TLR ligand-mediated signal transduction event is activation of the IL-1R-associated kinase IRAK (see page 6, paragraph 68, lines 3-7). TLR7 ligands include imidazoquinoline compounds such as imiquimod (see page 7, paragraph 77, lines 1-6).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Maibach et al. and wherein the improvement to the quality of the skin is by reversing changes in the dermis selected from the group consisting of diminution in the number and diameter of elastic fibers in the papillary dermis, atrophy of the dermis, reduction in subcutaneous adipose tissue, deposition of abnormal elastic materials in the upper dermis, or a combination thereof, because the above are all effects of aging as taught by Yu et al. (see elasticity (see column 9, lines 11-17 and 33-42)). Since, Maibach et al. teaches a treatment of age spots, which is age-related and hence is common among the elderly (see page 5, paragraph 45, lines 5-8), the above effects will obviously occur.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Maibach et al. and an agonist of at least one TLR, specifically TLR7, because of the following teachings: Maibach et al. teaches a method to treat age-spots comprising imiguimod and Raz et al. teaches that

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imiquimod is an agonist of TLR7. In addition, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

(2) Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,335,023 B1) in view of Maibach et al. (US 2003/0072724 A1).

Yu et al. teaches a method of treating cosmetic conditions or dermatoligical disorders comprising topically applying a topically acceptable vehicle, at least one compound selected from the group consisting of oligosaccharide aldonic acids, and a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42). Cosmetic conditions or dermatological disorders include changes associated with aging skin such as age spots, hyperpigmented skin and wrinkles (see claim 40). The compositions may be formulated as a solution, gel, lotion, cream, ointment, spray, or other forms acceptable for use on skin (see column 17, lines 49-52). Yu et al. teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis

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become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42; addresses claim 11).

Yu et al. does not specifically teach applying imiquimod to treat of wrinkles.

Maibach et al. teaches a treatment of an individual predisposed to or afflicted with skin hyperpigmentation, and comprises topically administering to the individual's affected skin area a pharmaceutical formulation containing a therapeutically effective amount of an agent active for treating skin hyperpigmentation (see page 4, paragraph 44, lines 1-7). A preferred embodiment is the treatment of age spots, which is agerelated and hence is common among the elderly (see page 5, paragraph 45, lines 5-8). Active agents include any compound that effectively treats warts such as imiquimod (see page 8, paragraph 92, lines 1-3 and 7). Treatment is to improve or remediate damage, which is exemplified in examples 4 and 5 by the lightened skin regaining essentially normal skin color after eight weeks of treatment (i.e. visibly reducing a skin change associated with aging and improving the quality of the skin; addresses claims 1, 7, 9 and 10).

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To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and applying imiguimod to treat of wrinkles because of the following teachings: (1) Yu et al. teaches a method of treating cosmetic conditions or dermatoligical disorders changes associated with aging skin such as age spots, hyperoignmented skin and wrinkles (see claim 40), with a cosmetic, pharmaceutical or topical agent such as imiquimod (see claims 10, 31 and 42); (2) Maibach et al. teaches a treatment for the age related skin condition age-spots or hyperpigmented skin, in which the active ingredient is imiguimod (see page 5, paragraph 45, lines 5-8 and see page 8, paragraph 92, lines 1-3 and 7); and (3) Yu'023 teaches that with increasing age and exposure of human to sun and other environmental traumas, cells divide at a slower rate showing marked irregularities in size, shape; orderliness; epidermis decrease (atrophy). The cells make the fibers of the dermis become smaller and sparser with increasing age. There is a great loss of collagen fibers resulting in looseness and easy stretchability of the skin; elastic fibers become abnormal so that the skin does not promptly snap back after being stretched. Degradation of these fibers, especially collagen is mainly responsible for wrinkling, laxness and loss of elasticity (see column 9, lines 11-17 and 33-42). Thus, one would be motivated to try the treatment of age related skin conditions such as wrinkles with the active ingredient imiguimod, because it also treats the age-related skin condition of agespots or hyperpigmented skin, which also results in the fibers of the dermis becoming smaller and sparser with increasing age.

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Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

The Applicant argues that as the amended claims now limit the compound to a specific class of IRM compounds that have related core chemical structures and operate via the same mechanisms of action.

The Examiner disagrees because compounds such as imidazonaphthyridine amine, thiazolquinoline and oxazolopyridine amine have different core structures. And although the compounds "might" have the same mechanism of action, one skilled in the art would need to determine each compound in each class of core structures are efficacious to improve the skin quality or treat wrinkles.

The Applicant further argues that the Yu et al. reference (US 6,335,023 B1) teaches imiquimod in a laundry list of widely unrelated drugs and one skilled in the art would not have understood this as a suggestion to combine with Maibach et al.

The Examiner disagrees because imiquimod is a claimed compound to treat skin conditions that improve skin quality (see claims 10, 31 and 42), and Maibach et al. provides the teaching that imiquimod is specifically responsible for treating age related conditions such as hyperpigmentation and age spots (see page 4, paragraph 44, lines 1-7; page 5, paragraph 45, lines 5-8 and page 8, paragraph 92, lines 1-3 and 7).

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

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/K. D. C./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617